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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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10/821,426

04/09/2004

Paul Alan Jass

CC-0312-04

1234

7590

07/31/2006

Richard J. Hammond
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EXAMINER

VALENROD, YEVGENY

ART UNIT

PAPER NUMBER

1621

DATE MAILED: 07/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|------------------------------------|--|
| Office Action Summary | Application No. 10/821,426 | Applicant(s) JASS ET AL. | |
| | Examiner Yevgeny Valenrod | Art Unit 1621 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>4/09/04; 4/29/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1 Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The said claims recite a ratio of solvent to probucol derivative, however it is unclear what units are assigned to the values in the said ratio.

The possibilities include the following: Wt : Vol, Wt : Wt. Moles : Moles.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2 Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In the claims in question the pH of the mixture formed in step two of the claimed process is reduced to less than 7. pH of the reaction mixture in the second step of the process is mentioned on page 8 of the specification, however no method of reducing pH and no values to which the pH is to be reduced are in the specification.

Claim Rejections - 35 USC § 103

3 Claims 1-4, 8-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jass (US 6,323,359) in view of Wang (US 3,485,843).

The inventive step of the instant application is the use of a ketone, optionally substituted aryl compound or optionally heteroaryl compound as a solvent for the deprotonation of a probucol compound.

Scope of prior art

Jass teaches preparation of water-soluble derivatives of probucol. In Column 3, lines 21-30 the method of deprotonating a probucol compound to form an ammonium or a metal salt is described. The substitutions in the probucol compound are described in column 2, lines 20-35 and their scope is largely in accordance with the substitution options of the probucol compounds in the instant application, difference being that R1 and R2 can have up to 8 carbons in the reference and only up to 6 in the application and R3, R4, R5, R6 can have up to 4 carbons in the reference and up to 6 in the application. In example 1 in column 4, lines 50-60 the process of deprotonation is described in detail. The solvent is added at 20-25⁰C (line53), however on line 58 Jass says that there is a temperature drop from 35⁰C to 22⁰C. This indicates that the reaction was proceeding at 35⁰C (limitations of claims 8-10).

Ascertaining the difference between prior art and the instant claims

Jass teaches the process of deprotonating probucol compounds and subsequently reacting the obtained salt with electrophiles. However, Jass only teaches

the use of THF or acrylonitrile as a solvent for deprotonation and does not teach the use of a ketone, optionally substituted aryl compound or optionally heteroaryl compound for the same purpose.

Secondary reference

Wang teaches preparation of ammonium salts of probucol compounds from their protonated derivatives (column 1, lines 19-33) by treating the protonated probucol derivative with piperazine in acetone (column 1 lines 48-52). Wang is able to recover the formed salt by cooling the reaction mixture and allowing the product to precipitate (column 2 lines 8-10).

Motivation to combine

Ammonium salts of probucol can be conveniently separated from the reaction mixture by cooling the mixture in acetone and precipitating the desired product (Wang, Column 2, lines 8-10). One wishing to have the option of easily separating the ammonium salt from the reaction mixture and then using a predetermined amount of that salt for further reaction with electrophiles (as taught by Jass) would be motivated to use acetone as a solvent for the process of deprotonating probucol compounds (as taught by Wang). One of ordinary skill in the art would therefore be motivated to combine with reasonable expectation of success Wang's process of forming the ammonium salt in acetone and Jasses process of making probucol derivatives. The expected result would be production of probucol derivatives where acetone is used in the deprotonation step (step 1 according to the instant invention).

Conclusion

Claims 1-15 are pending.

Claims 1-15 are rejected.

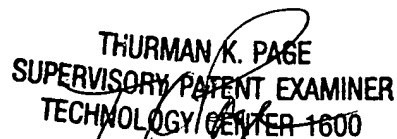
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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